



NEWS RELEASE

Omeros Announces Positive Data from OMS721 Phase 2 Clinical Trial in Renal Diseases

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-- Pursuing Breakthrough Therapy Designation in IgA Nephropathy (Berger's Disease) --

SEATTLE--(BUSINESS WIRE)--Oct. 17, 2016-- Omeros Corporation (NASDAQ: OMER) today announced positive data from the company's Phase 2 clinical trial of OMS721 for the treatment of kidney disorders, none of which currently have an approved treatment and all of which frequently lead to end-stage renal disease and dialysis. Statistical significance ($p \leq 0.017$) was achieved on key endpoints of improvement in renal function. Omeros also reported the outcome of a recent FDA meeting regarding breakthrough therapy designation for OMS721 in immunoglobulin A (IgA) nephropathy (also known as Berger's disease). Based on that meeting, Omeros is pursuing FDA breakthrough therapy designation. In addition to the Phase 2 program in renal diseases, OMS721 is being evaluated in a Phase 3 program for patients with atypical hemolytic uremic syndrome (aHUS) and in a Phase 2 program for patients with thrombotic microangiopathies (TMAs), including hematopoietic stem cell transplant-associated TMAs and thrombotic thrombocytopenic purpura. OMS721 is Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), the effector enzyme of the lectin pathway of the complement system.

The Phase 2 open-label renal trial is evaluating OMS721 across four different types of complement-associated kidney diseases: IgA nephropathy (i.e., Berger's disease), membranous nephropathy, lupus nephritis, and complement component 3 (C3) glomerulopathy. Each of the four renal-disease cohorts was planned to enroll four

patients. All patients in the trial must have high levels of urinary protein (a marker used by nephrologists to assess disease activity) despite ongoing treatment with a stable corticosteroid dose; these inclusion criteria ensure that study patients are unlikely to improve spontaneously. Patients are treated with OMS721 for a total of 12 weeks: four weeks maintaining their entry corticosteroid dose; four weeks of corticosteroid tapering, if tolerated; and four weeks of resultant corticosteroid dose maintenance. Patients are then followed post-treatment for six weeks. The key efficacy measures are urine albumin-to-creatinine ratios (uACRs) throughout the trial and change in 24-hour urine protein levels from baseline to the end of treatment. To date, two patients with IgA nephropathy, two patients with membranous nephropathy, and two patients with lupus nephritis have completed the trial. Additional patients have been enrolled and are being dosed.

The IgA nephropathy patients demonstrated a clinically meaningful and statistically significant decrease in uACRs; lower uACRs are associated with improved renal survival. Treatment effects across the two patients were highly consistent. The mean baseline uACR was 1264 mg/g and reached 525 mg/g at the end of treatment ($p = 0.011$), decreasing to 128 mg/g at the end of the follow-up period. Measures of 24-hour urine protein excretion tracked uACRs, with a mean reduction from 3156 mg/day to 1119 mg/day ($p = 0.017$). Both patients experienced reductions of approximately 2000 mg/day and both achieved a partial remission (defined as greater than 50 percent reduction in 24-hour urine protein excretion and/or resultant protein excretion less than 1000 mg/day; complete remission defined as protein excretion less than 300 mg/day). The magnitude of the 24-hour proteinuria reductions in both IgA nephropathy patients is associated with significant improvement in renal survival. Also, during the trial, daily steroid doses for both patients were able to be reduced substantially (60 mg to 0 mg and 30 mg to 5 mg).

The two patients with membranous nephropathy demonstrated reductions in uACR during treatment. One patient had a decrease from 1003 mg/g to 69 mg/g, maintaining this low level throughout the follow-up period, while the other decreased from 1323 mg/g to 673 mg/g with a variable course after treatment. The first patient showed a marked reduction in 24-hour urine protein excretion (10771 mg/day to 323 mg/day), achieving partial and nearly complete remission, while the other remained essentially unchanged (4272 mg/day to 4502 mg/day). These combined effects did not reach statistical significance. Daily steroid doses were able to be tapered in the two patients from 10 mg to 5 mg and from 30 mg to 15 mg.

The time course of changes in uACR during treatment was consistent across all four patients with IgA and membranous nephropathies. Preliminary analysis demonstrated no evidence of treatment effect in patients with lupus nephritis. No patients with steroid-dependent C3 glomerulopathy, an extremely rare disorder, have yet been enrolled. There is strong published evidence of lectin pathway involvement in the pathophysiology of IgA nephropathy and membranous nephropathy, with the evidence of lectin pathway involvement weaker for lupus.

Consistent with the other clinical trials with OMS721, no significant safety concerns have been observed. The most

commonly reported adverse events in this trial have been anemia and fatigue, both commonly seen in these populations. Omeros plans to submit these data for presentation at the European Renal Association-European Dialysis Transplant Association 54th Annual Congress to be held in June 2017.

Given the data seen in these renal patients, Omeros discussed with the FDA's Division of Cardiovascular and Renal Products the potential treatment effects and the possibility of a rapid and abbreviated path to approval. Based on the FDA's guidance, Omeros is pursuing breakthrough therapy designation for OMS721 in IgA nephropathy and is amending the current protocol for its Phase 2 renal trial to assess five OMS721-treated and five placebo-treated patients with the disease. These patients need not be steroid-dependent, which is expected to greatly accelerate enrollment. Achieving statistical significance is not required. In parallel to completing the limited enrollment for breakthrough designation, Omeros plans to advance OMS721 rapidly through its IgA nephropathy development program to support both U.S. and international marketing authorizations. After additional OMS721 data have been collected in membranous nephropathy patients, Omeros may also pursue breakthrough therapy designation for that indication.

No treatments are currently approved for either IgA nephropathy or membranous nephropathy. IgA nephropathy is the most common primary glomerular disease globally. With an annual incidence of approximately 2.5 per 100,000, it is estimated that 1 in 1400 persons in the U.S. will develop IgA nephropathy. As many as 40 percent of them will develop end-stage renal disease. The annual incidence of membranous nephropathy is approximately 10-12 per 1,000,000. Patients with membranous nephropathy can have a variable clinical course, but approximately 25 percent will develop end-stage renal disease.

"While the patient numbers are small, the consistency in the patients' clinical courses in these severe diseases is impressive," stated Professor Michal Nowicki, President of the Polish Society of Nephrology and OMS721 clinical investigator. "The responses we have observed in patients with aHUS, including reversal of renal failure and dialysis cessation, and these renal data demonstrate the potential of lectin pathway inhibition in nephrology."

Omeros' Phase 3 OMS721 aHUS program continues to progress with Phase 3 enrollment planned to open late this year. The current TMA Phase 2 clinical trial continues steadily to enroll and treat aHUS patients, gathering data to support a biological license application (BLA). Omeros plans to submit aHUS data from this study for presentation at the International Society of Nephrology World Congress of Nephrology in April 2017. The OMS721 program also continues to support compassionate use in Europe and the FDA has approved OMS721 for compassionate use in the U.S.

"We are very excited about these additional data in serious renal diseases," stated Gregory A. Demopoulos M.D., chairman and chief executive officer of Omeros. "The Phase 3 clinical trial for aHUS is expected to open for enrollment later this year, and the clinical data from these IgA and membranous nephropathy patients increase the

number of commercial avenues for OMS721. Current understanding of the importance of the lectin pathway's role across inflammatory diseases is expanding, and we look forward to continuing to work with the FDA and international regulatory agencies to develop an efficient and rapid path to approval for OMS721 in the treatment of aHUS, IgA and membranous nephropathies and a number of other diseases.”

Additional data from Omeros' OMS721 program are expected later this year.

About Omeros' MASP-2 Program

Omeros controls the worldwide rights to MASP-2 and all therapeutics targeting MASP-2, a novel pro-inflammatory protein target involved in activation of the complement system, which is an important component of the immune system. The complement system plays a role in the inflammatory response and becomes activated as a result of tissue damage or microbial infection. MASP-2 is the effector enzyme of the lectin pathway, one of the principal complement activation pathways. Importantly, inhibition of MASP-2 does not appear to interfere with the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection, and its abnormal function is associated with a wide range of autoimmune disorders. MASP-2 is generated by the liver and is then released into circulation. Adult humans who are genetically deficient in one of the proteins that activate MASP-2 do not appear to be detrimentally affected by the deficiency. Omeros has received both Orphan Drug status and Fast Track designation from the U.S. FDA for its lead human MASP-2 antibody OMS721. Following discussions with both the FDA and the European Medicines Agency, a Phase 3 program for OMS721 in atypical hemolytic uremic syndrome is in progress. Also, two Phase 2 trials are ongoing with one evaluating OMS721 in glomerulonephropathies, which has generated positive data in patients with immunoglobulin A (IgA) nephropathy and with membranous nephropathy, and the other in thrombotic microangiopathies (TMAs), including hematopoietic stem cell transplant-associated TMA and thrombotic thrombocytopenic purpura. In addition to potential intravenous administration, Omeros plans to commercialize OMS721 for one or more therapeutic indications as a subcutaneous injection and is also developing small-molecule inhibitors of MASP-2. Based on requests from treating physicians, Omeros has established a compassionate-use program for OMS721, which is active in both the U.S. and Europe.

Omeros also has identified MASP-3 as the protein that is critical to the activation of the complement system's alternative pathway in humans, which is linked to a wide range of immune-related disorders. In addition to its lectin pathway inhibitors, the company is advancing its development of antibodies and small-molecule inhibitors against MASP-3 to block activation of the alternative pathway.

About Omeros Corporation

Omeros is a biopharmaceutical company committed to discovering, developing and commercializing both small-

molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Part of its proprietary PharmacoSurgery® platform, the company's first drug product, OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3%, was broadly launched in the U.S. in April 2015. OMIDRIA is the first and only FDA-approved drug (1) for use during cataract surgery or intraocular lens (IOL) replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain and (2) that contains an NSAID for intraocular use. In the European Union, the European Commission has approved OMIDRIA for use in cataract surgery and lens replacement procedures to maintain mydriasis (pupil dilation), prevent miosis (pupil constriction), and to reduce postoperative eye pain. Omeros has clinical-stage development programs focused on: complement-related thrombotic microangiopathies; complement-mediated glomerulonephropathies; Huntington's disease and cognitive impairment; and addictive and compulsive disorders. In addition, Omeros has a proprietary G protein-coupled receptor (GPCR) platform, which is making available an unprecedented number of new GPCR drug targets and corresponding compounds to the pharmaceutical industry for drug development, and a platform used to generate antibodies.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the "safe harbor" created by those sections for such statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions and variations thereof. Forward-looking statements are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. Omeros' actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, risks associated with product commercialization, Omeros' unproven preclinical and clinical development activities, regulatory oversight, intellectual property claims, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading "Risk Factors" in the company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2016. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and the company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

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